UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,137	10/06/2006	Andrew Douglas Baxter	GJE-7705	7780

23557 7590 06/25/2008

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER	
GUDIBANDE, SATYANARAYAN R	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
06/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,137	BAXTER ET AL.	
	Examiner	Art Unit	
	SATYANARAYANA R. GUDIBANDE	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16 and 17* is/are pending in the application.

4a) Of the above claim(s) *3-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/25/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of group XII invention and election of nylidrin as the species corresponding formula I, election of rheumatoid arthritis as the disease condition and cortisol as the another therapeutic agent in the reply filed on 3/13/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is also acknowledged that claim 15 has been canceled and claims 1 and 16 have been amended so that claim 1 corresponds to the elected group.

Claims 1-14, 16 and 17 are pending.

Claims 3-14 have been withdrawn from further consideration as being drawn to non-elected invention.

Claims 1, 2, 16 and 17 are examined on the merit.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. either or both 119(e) or 120 as follows:

This application repeats a substantial portion of prior Application Nos. UK 0406016.6 filed 3/17/2004, UK 0418556.7 filed 8/19/2004 and UK 0422880.5 filed 10/14/2004, and adds

and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78. Therefore, the subject matter added to the disclosure in the instant application based on the PCT/GB05/01031 filed 3/17/05 does not get priority beyond the filing date of the PCT filed on 3/17/05.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recite a limitation "compound in the form of the enantiomer or diastereomer that has relatively little or no activity at the α or β adrenoceptor". The claim as recited as the term "α or β adrenoceptor" lacks antecedent basis in the base claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant invention, applicants claim a method for the treatment or prevention of a condition associated with T-cell proliferation or that is mediated by pro- and/or anti-inflammatory cytokines by administering a compound of formula I wherein the compound is selected from bufeniode, denopamine, fenoterol, ifenprodil, isoxsuprine, labetalol, medroxalol, mesuprine, nylidrin, protokylol, ractopamine, ritodrine, salmefamol and sulfinatol.

Claim 1 as recited encompasses a method of treating or preventing any and all known and unknown disease conditions associated with T-cell or mediated by pro- and/or anti-inflammatory cytokines. However, the specification as disclosed does not adequately support the claim as recited commensurate with the scope of the claim. The term "prevent or prevention" is not found in the specification as originally disclosed on 8/30/06. The specification also discloses one example wherein labetalol is administered to a rat model for arthritis. Hence the elected species has not been used in the specific example to show that applicants had possession of the instant invention.

The MPEP clearly states that the purpose of the written description is to ensure that the inventor had possession of invention as of the filing date of the application, of the subject matter later claimed by him. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997). The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the application. These include, "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed invention is sufficient" MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated: "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations

other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further the claim 17 of the instant application requires administration another therapeutic agent such as cortisol (elected species) to treat or prevent the disease condition associated with T-cell proliferation. However, no examples of such administration to treat or prevent any of the disease conditions are disclosed in the instant specification.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

Therefore, the claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102

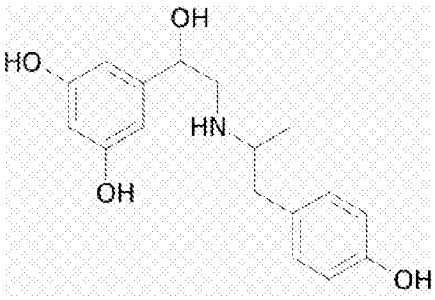
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Holen, APMIS, 1998, pages 849-857, Vol. 106.

In the instant invention, applicants claim a method for the treatment or prevention of a condition associated with T-cell proliferation or that is mediated by pro- and/or anti-inflammatory cytokines by administering a compound of formula I wherein the compound is selected from bufeniode, denopamine, fenoterol, ifenprodil, isoxsuprine, labetalol, medroxalol, mesuprine, nylidrin, protokylol, ractopamine, ritodrine, salmefamol and sulfinatol.

The compound fenoterol taught by Holen has the following structure,



that reads on the formula I of instant claim 1. The reference also reaches that administration of fenoterol to patients was performed to study the effect of the drug on T-cell proliferation. The results indicated that administration of fenoterol a β2-adrenoceptor agonist influenced T-cell growth and function (abstract). The reference also discloses that β2-adrenoceptor agonists are widely used in treatment of asthma which is a chronic disorder of airway inflammation (page 849, paragraphs 1 and 2). This meets the limitations of claim 1. Hence the reference of Holen anticipates instant invention.

Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US 4,086,363 issued to Cervoni.

In the instant invention, applicants claim a method for the treatment or prevention of a condition associated with T-cell proliferation or that is mediated by pro- and/or anti-inflammatory cytokines by administering a compound of formula I wherein the compound is selected from bufeniode, denopamine, fenoterol, ifenprodil, isoxsuprine, labetalol, medroxalol, mesuprine, nylidrin, protokylol, ractopamine, ritodrine, salmefamol and sulfinatol.

The reference reaches that administration of nylidrin (elected species) to patients for the treatment of asthma and the prevention of asthmatic symptoms (column 1, lines 4-5). The reference discloses that nylidrin is a β-adrenergic stimulator and useful in the treatment of asthma which is a chronic disorder of airway inflammation. Since nylidrin is administered to patients suffering from asthma, it is inherent that it is treating the disease condition mediated by

pro- and/or anti-inflammatory cytokines. This meets the limitations of claim 1. Hence the reference of Cervoni anticipates instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,086,363 issued to Cervoni as applied to claim 1 above, and further in view of WO 03/092617 of Jost-Price, et al.

In the instant invention, applicants claim a method for the treatment or prevention of a condition associated with T-cell proliferation or that is mediated by pro- and/or anti-

inflammatory cytokines by administering a compound of formula I wherein the compound is selected from bufeniode, denopamine, fenoterol, ifenprodil, isoxsuprine, labetalol, medroxalol, mesuprine, nylidrin, protokylol, ractopamine, ritodrine, salmefamol and sulfinatol.

The reference reaches that administration of nylidrin (elected species) to patients for the treatment of asthma and the prevention of asthmatic symptoms (column 1, lines 4-5). The reference discloses that nylidrin is a β-adrenergic stimulator and useful in the treatment of asthma which is a chronic disorder of airway inflammation. Since nylidrin is administered to patients suffering from asthma, it is inherent that it is treating the disease condition mediated by pro- and/or anti-inflammatory cytokines. This meets the limitations of claim 1. Hence the reference of Cervoni anticipates instant invention.

However, the reference of Cervoni, does not teach a combination of drugs for the treatment or prevention of disease associated T-cell proliferation or mediated by pro- and/or anti-inflammatory cytokines.

The reference of Jost-Price discloses combination of β-adrenergic receptor ligand and a steroid (claim 5 of the cited reference, page 18). The β-adrenergic receptor ligand selected from finoterol, labetol, medroxalol, etc., (claim 6 of the cited reference) and the steroid chosen from 6-β-hydroxycortisol, cortisone, cortisone acetate, etc., (claim 51 of the cited reference on page 25). The cited reference of Jost-Price also discloses that inflammatory skin disorders occurs in people who have family history of asthma (page 1, line 14) and psoriasis a common chronic proliferative skin disease (page 1, line 22) has some association with arthritis (page 1, line 30). The reference also teaches that TNF-alpha is a major mediator of inflammation (page 2, line 14).

It would have been obvious to one of ordinary skill in the art at the time the invention combine the teachings of Cervoni and Jost-Price to arrive at the instant invention. The skilled artisan would have been motivated to do so given the fact that arthritis is associated to chronic proliferative skin disease such as psoriasis which occurs in people who have a family history of asthma. Josh-Price uses a combination of therapy of β-adrenergic receptor ligand such as finoterol, labetol, medroxalol, etc., whose structural features corresponds to formula I of instant invention (including the elected species nylidrin) along with a steroid such as cortisol. There would have been a reasonable expectation of success to use a combination of nylidrin with cortisol in the instant invention, given the fact that Jost-Price used the afore-mentioned combination drug to treat inflammatory skin disorders and the skin disorders are associated with arthritis as suggested by the Jost-Price.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satyanarayana R Gudibande/
Examiner, Art Unit 1654

/Andrew D Kosar/
Primary Examiner, Art Unit 1654